K022532

FEB 12 2003

510(k) Summary of Safety and Effectiveness

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Application Information:

Date Prepared:	July 31, 2002
Submitter:	TissueLink Medical Inc.
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Device Information:

Trade Name:	TissueLink Bipolar Floating Ball device
Common Name:	Electrosurgery Cauterizing Pen
Classification Name:	Electrosurgical cutting and coagulation device and accessories, 21CFR 878.4400

Predicate Devices:

Claim of Substantial Equivalence of the TissueLink Bipolar Floating Ball device is made to:

Identical device, TissueLink Bipolar Floating Ball, K#020574

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2003

Ms. Vicki S. Anastasi
Director, Regulatory Affairs
TissueLink Medical, Inc.
One Washington Center, Suite 400
Dover, New Hampshire 03820

Re: K022532
Trade/Device Name: TissueLink Bipolar Floating Ball Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: November 13, 2002
Received: November 14, 2002

Dear Ms. Anastasi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use Statement

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510(k) Number (if known): K022532

Device Name: TissueLink Bipolar Floating Ball device

Indications for Use:

The TissueLink Bipolar Floating Ball device is a sterile, single use electrosurgery device intended to be used in conjunction with an electrosurgical generator for delivery of radiofrequency current and saline for hemostatic sealing and coagulation of soft tissue and bone at the operative site. It is intended for, but not limited to, endoscopic and open abdominal, orthopaedic, spine and thoracic surgery. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109) Optional Format 1-

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K022532